



PharmacyChecker.com Verification Program

Guide and Standards 1.3

Protecting the Public Health:

Helping Consumers Find Information About

Safe Online Pharmacies that Sell Affordable Medications

October 2014

White Plains, New York

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PharmacyChecker.com Verification Program Guide and Standards

(Standards Document 1.3)

PharmacyChecker.com protects the public health by helping to maximize access to safe and affordable medication.

INTRODUCTION

Maximizing access to safe and affordable medication is a global public health priority.¹ Each year about 50 million Americans between the ages of 18 and 64 do not fill a prescription for cost-related reasons.² According to the Harvard School of Public Health, over half of Americans who do not take prescription medication due to cost report becoming sicker. That means potentially 25 million Americans become sicker each year because they can't afford prescribed medication.³

The mission of PharmacyChecker.com is to help consumers find safe and affordable medication when searching on the Internet. PharmacyChecker.com's programs protect the public health by reducing the number of people who fail to take their prescribed medication due to cost and greatly reducing the chance of them buying from a dangerous pharmacy website.

The Internet presents serious dangers to the public health in the form of "rogue" online pharmacies, health scams, and counterfeit drugs. At the same time, many drugs prescribed in the U.S. are far less expensive in other countries – and they are available online. How can people who need affordable medication from abroad protect themselves?

PharmacyChecker.com was launched in 2003 to verify the credentials of online pharmacies and compare their drug prices to help consumers searching for affordable prescription medication. The information

¹ World Health Organization, "The World Medicines Situation," 3rd ed., 2011, Geneva, see http://www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch6_wPricing_v6.pdf [Last accessed 10/10/2014].

² S. R. Collins, R. Robertson, T. Garber, and M. M. Doty, "Insuring the Future: Current Trends in Health Coverage and the Effects of Implementing the Affordable Care Act", *The Commonwealth Fund*, April 2013.

³ *USA Today*/Kaiser Family Foundation/ Harvard School of Public Health, *Health Care Costs Survey* (conducted April 25 –June 9, 2005). The survey finds that 20% of respondents, adult Americans, report not filling a prescription due to cost; 54% of those respondents said their condition got worse as a result. Extrapolated to the 2012 population of adults 18 and older, which is 234,564,071, the number is approximately 25 million people. See <http://kff.org/health-costs/poll-finding/health-care-costs-survey-summary-and-chartpack/> [Last accessed 7/5/2014].

on PharmacyChecker.com is accessible for free. Empirical data from published studies⁴, and over a decade of experience, demonstrate that consumers are very safe if they order medications online from websites authorized to publish the PharmacyChecker.com Verification Program Seal (the “Seal”).

This document identifies PharmacyChecker.com Verification Program standards. The standards are agreed to by online pharmacies applying to the [Verification Program](#).

PharmacyChecker.com Verification Program

PharmacyChecker.com operates a Verification Program (the “Program”) that enables physical and online pharmacies meeting high safety standards to become Members. A valid member is authorized to publish the PharmacyChecker.com Seal (the “Seal”) (see sample below), which includes its website address and links to its pharmacy profile on www.PharmacyChecker.com.



Prescription orders placed with an online pharmacy publishing a valid PharmacyChecker.com Seal are filled by licensed pharmacists and pharmacies pursuant to a valid prescription.

What are online pharmacies?

Online pharmacies are websites on which prescription orders are placed that are, in turn, filled by licensed pharmacies (“physical pharmacies”).⁵ Sometimes online pharmacies are owned and operated by a licensed pharmacy and orders are filled by that one pharmacy. In other cases online pharmacies partner with multiple pharmacies. In this latter model, an order is placed on a website and referred to one of several licensed pharmacies that dispenses prescription drugs by mail. *The Program meets its goals by verifying the licenses of all pharmacies that fill orders placed with online pharmacy Members.*

The Program is open to domestic physical pharmacies, international physical pharmacies, domestic online pharmacies, international online pharmacies, international pharmacy operations (usually pharmacies in free trade zones), wholesale pharmacies, and veterinary pharmacies. These different designations for pharmacy and website Members of the Program are defined in *Appendix A*.

⁴ Bate, Roger, Ginger Zhe Jin and Aparna Mathur, “In Whom We Trust: The Role of Certification Agencies in Online Drug Markets,” *The B.E. Journal of Economic Analysis & Policy*. Volume 14, Issue 1, Pages 111–150, ISSN (Online) 1935-1682, ISSN (Print) 2194-6108, DOI: 10.1515/bejeap-2013-0085, December 2013.

⁵ In this guide we use the phrase “physical pharmacy” instead of the more commonly used “brick-and-mortar pharmacy” to describe the actual place from which medication is shipped. The latter phrase is usually associated with a local pharmacy accessible by pedestrians. While some Members of PharmacyChecker.com are “walk-in” pharmacies, other pharmacies that work with online pharmacies only operate by mail-order.

International online pharmacies and international physical pharmacies must meet additional pharmacy practice standards and may not sell controlled medicines into the United States.

For the purposes of this document, all applicants and Members that *dispense* prescription drugs are referred to as *pharmacies* and/or *international pharmacies* (both are “*physical pharmacies*”), and all websites that *market and sell* prescription drugs are referred to as *online pharmacies* or *international online pharmacies*. *Websites that market online prescription drugs but do not take orders or facilitate transactions are not online pharmacies.*

To gain approval in the Program, applicant online pharmacies may only process orders filled by a physical pharmacy that is also verified by PharmacyChecker.com, meaning “approved” in the Program. The Program Standards are divided into two member classifications: A) Physical pharmacies and B) Online pharmacies.

A. Program Standards for Physical Pharmacies

Pharmacies that fill prescription orders placed over the Internet for their own or other PharmacyChecker.com-approved online pharmacies must meet the following standards to be approved in the Program:

1. **Licensure.** The pharmacy must be licensed or registered in good standing.
2. **DEA registration.** If dispensing controlled substances within or into a U.S. state, the pharmacy must be registered with the United States Drug Enforcement Administration (DEA).
3. **Disciplinary history.** The pharmacy, pharmacist-in-charge, pharmacist manager (or equivalent name for head of a pharmacy) must not have been subject to significant recent and/or repeated disciplinary sanctions that affect the safety of the pharmacy operation.
4. **Validity of prescription.** The pharmacy must only dispense prescription drugs upon receipt of a valid prescription issued by a licensed medical practitioner authorized to prescribe in the jurisdiction where licensed. This requirement pertains to medication requiring a prescription based on where the medication is to be shipped. Thus, if a consumer in the U.S. orders a drug to be dispensed from a Canadian pharmacy for which a prescription is required in the U.S. but not in Canada, the Canadian pharmacy must still require a prescription. A “valid prescription” is one issued pursuant to a legitimate patient-prescriber relationship, which requires the following to have been established: a) The patient has a legitimate medical complaint; b) A face-to-face physical examination adequate to establish the legitimacy of the medical complaint has been performed by the prescribing practitioner, or through a telemedicine practice explicitly permitted under federal or state laws or regulations; and c) A logical connection exists between the medical complaint, the medical history, and the physical examination and the drug prescribed.
5. **Legal compliance.** The pharmacy must comply with all provisions of law governing its operation in the jurisdiction where the pharmacy is located.
6. **Drug approvals:** The pharmacy must not dispense medications that have not been approved for sale in at least one of the following countries: Australia, Canada, European Union, India (subject to additional

restrictions, as per PharmacyChecker Inspection Program requirements 5.1; see Appendix B), Israel, New Zealand, Singapore, South Africa, Turkey, United Kingdom, or the United States. Thus, an international prescription dispensary is limited to selling only prescription products approved for sale in the aforementioned countries.

7. **Privacy.** The pharmacy must protect a customer's personal and financial information in accordance with national law in the seller's country, and, if relevant, must make use of Secure-Socket Layer or equivalent technology for the online transmission of a customer's personal and financial data.
8. **Compounding pharmacies:** If the pharmacy markets compounding pharmacy services that include the manufacture of sterile drugs products for bulk sales to hospitals and other healthcare providers, the pharmacy must show proof of U.S. FDA registration as an Outsourcing Facility for human drug compounding as provided under Section 503B of the Federal Food, Drug, and Cosmetic Act. For more information see the FDA [website](#).
9. **Pharmacy inspection and location.** The pharmacy must be inspected by its governing regulatory authority domiciled in Australia, Canada, Israel, New Zealand, South Africa, United Kingdom, or the United States, and an additional inspection by PharmacyChecker.com is required for pharmacies in India and Turkey, and international pharmacy operations on free trade zones in Barbados, Mauritius, and Singapore to ensure high standards in line with pharmacies in the United States. Inspections focus on personnel, prescription processing systems, drug safety, sanitary conditions, storage, and mail order safety practices. See Appendix B for the PharmacyChecker.com Inspection Program Standards 5.1.
10. **Generic substitution.** International pharmacy applicants or Members may not substitute a generic prescription drug for a brand name drug without the consent of the customer when dispensing a prescription internationally. [This adds a restriction not imposed on many pharmacies in a domestic setting, such as in most U.S. states, which often allow or require pharmacists to automatically substitute a generic unless a prescription states "dispense as written."]
11. **No exports for re-sale.** The pharmacy must not 1) intentionally ship medication for re-sale in the U.S. except in compliance with U.S. drug importation laws, and 2) ship prescription orders exceeding a three-month supply unless medically necessary.

B. Program Standards for Online Pharmacies (“Websites”)

Online pharmacies (websites that market and sell prescription drugs) that seek Membership or are currently Members of the PharmacyChecker.com Verification Program must meet the following standards:

1. **Prescription requirement.** Website must clearly communicate that a customer’s valid prescription, as defined above in A.4, is required for the purchase of prescription medication.
2. **Affiliating pharmacy.** Website must only refer prescription drug orders to pharmacies that are Members of PharmacyChecker.com Verification Program.
3. **Mailing address and phone number.** Website must publish a mailing address and phone number at which a customer can make contact for assistance.
4. **Privacy.** Website must not share a customer’s personal or financial information except where necessary to process the prescription order. If a website requires or permits the online transmission of personal and financial data, the information must be transmitted in accordance with national law in the website’s country, and must include the use of Secure-Socket Layer or equivalent technology for its transmission to protect a customer’s personal health and financial information.
5. **Pharmacist letter.** For each pharmacy which dispenses prescription orders referred by applicant or Member website, PharmacyChecker.com must receive a letter from that pharmacy’s pharmacist-in-charge, pharmacist manager, or equivalent head pharmacist, attesting that his or her pharmacy dispenses prescription orders referred by applicant or Member website. The letter must read as follows:

"The undersigned is the pharmacist manager of [Pharmacy Name] located at [Pharmacy Address]. I hereby certify to PharmacyChecker that my pharmacy fills orders generated or initiated by [Name of Online Pharmacy] from [Online Pharmacy URL]. If at any time my pharmacy ceases filling such orders, we will immediately notify PharmacyChecker."

6. **Website transparency.** Website must not engage in practices or extend offers on its website that deceive or defraud patients as to any material detail regarding the practice, its staff, prescription drugs, or financial transactions.
7. **Affiliated websites.** Website and any person or entity that exercises control over it must not link or otherwise refer customers to pharmacies or prescription drug selling websites that are not Members of the PharmacyChecker Verification Program.
8. **Pharmacist Consultation.** Website must be able to make available a licensed pharmacist to consult with a customer about a prescription order in progress.
9. **Disclosure of Pharmacy Location.** Website must disclose country locations of affiliated pharmacies that dispense prescription drugs and inform customers of the country of the dispensing pharmacy before charges are made. For example, if a consumer places an order with a website based in Canada, the website must inform the customer if the prescription drug will be dispensed by a pharmacy in a country other than Canada.

APPENDIX A

Definitions

Approved Online Pharmacy: A drug-selling website that is verified by PharmacyChecker.com as meeting PharmacyChecker.com's standards.

Approved Pharmacy: A pharmacy that is verified by PharmacyChecker.com as meeting PharmacyChecker.com's requirements for filling prescription orders placed over the Internet.

International Online Pharmacy: A company that markets and sells prescription medication over the Internet through the same website to consumers in more than one country.

International Pharmacy: A mail-order pharmacy that dispenses prescription medication to consumers in more than one country. An international pharmacy can also serve local residents where it operates.

International Prescription Dispensary: An international pharmacy that only dispenses prescription medication to consumers in other countries. These pharmacies are generally located in free trade zones.

Local Pharmacy: A walk-in pharmacy.

Online Pharmacy: A company that markets and sells prescription medication over the Internet through a website.

Pharmacy: A company that dispenses prescription medication.

Physical Pharmacy: A space used for dispensing prescription medication.

Veterinary Pharmacy: A pharmacy that sells medications for use by animals.

Wholesale Pharmacy: A pharmacy that sells medication to other pharmacies and authorized pharmaceutical distributors.

Appendix B



INTERNATIONAL PHARMACY INSPECTION PROGRAM

June 2014

**PharmacyChecker
Inspection Program Requirements 5.1**

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I. Standard Operating Procedures Document

Pharmacy must have a Standard Operating Procedures (SOP) document that describes the policies and procedures that are followed and practiced to ensure that the pharmacy meets all of the requirements contained herein. At a minimum, the SOP will describe the pharmacy's basic practices as they relate to the following areas:

- A. Pharmacy personnel
- B. Prescription processing system
- C. Drug safety
- D. Sanitary condition of pharmacy
- E. Storage
- F. Mailing prescriptions

II. Personnel

Pharmacy staff must be sufficiently qualified and competent to carry out required duties.

Requirements:

- 2.1 All medications dispensed must be checked by a licensed pharmacist.
- 2.2 All staff members must be fully aware of confidentiality and subject to an agreement to protect health information.
- 2.3 New staff must receive appropriate training to ensure consistency of service.
- 2.4 Staff must be provided with, and aware of, SOPs to ensure consistency of service.

III. Prescription Processing System

Prescriptions must be processed in a methodical, consistent manner that ensures confidentiality, accuracy and safety of dispensed medication.

Requirements:

Recording of Health Information

The pharmacy's records must be kept in a manner that is readily accessible while ensuring confidentiality.

- 3.1 All patient information must be stored in a manner that ensures confidentiality of such information.
- 3.2 Procedures must be maintained to provide for the secure storage and replication of the pharmacy's information system and data.

Dispensing Process

"Dispensing" means the process of a pharmacist providing a patient with each item pursuant to a prescription. Dispensing includes all the steps that occur from receipt of the prescription at the pharmacy to the prescribed item being delivered to the patient.

"Dispensing Pharmacy" means the pharmacy subject to inspection under this program that mails the prescription to a patient.

"Partner" means licensed pharmacist affiliated with a PharmacyChecker.com-approved online pharmacy.

There must be in place a dispensing procedure that ensures that the appropriate product is selected and dispensed correctly and efficiently.

- 3.3 All prescriptions dispensed must be checked by signature or recorded electronically by a licensed pharmacist before shipment to the patient.
- 3.4 The Dispensing Pharmacy or a licensed pharmacist working with a PharmacyChecker.com-approved Partner must verify the authenticity of the prescription and check that the prescription is appropriate, correct and complete. The roles of the pharmacy and the Partner must be defined in writing and included in the SOPs.

- 3.5 A licensed pharmacist must ensure that the dispensed medication is selected and labeled correctly and sufficiently to ensure appropriate use.
- 3.6 Labels must include the following information:
- Patient name
 - Prescriber name or identification code
 - Name of medication, strength and quantity
 - Easily recognizable instructions for taking medication
 - Prescription number (unique identifying number or code of the prescription issued by the pharmacy for reference)
 - Date prescription was filled
 - Initials of the pharmacist performing final verification
 - Name of the pharmacy, address and contact details
 - Font size and quality of the print must be sufficient to read easily
- 3.7 Appropriate cautionary and advisory labels must be used to assist the patient in using and storing the medication per PharmacyChecker policy.
- 3.8 Quantities for medication dispensed to an individual in the United States must not exceed a three-month supply, unless medically necessary (excluding refills).
- 3.9 If there is a guaranteed time by which the Pharmacy or the Partner indicates medication will be delivered, it must be met. A procedure must be available when delivery of medication within the guaranteed timeframe is not possible. The roles of the Pharmacy and the Partner must be defined in writing and included in the Standard Operating Procedures.
- 3.10 Pharmacist of dispensing pharmacy or Partner must check medication history of the patient for consistency of treatment and possible interactions and contact the prescriber when clinically significant interactions are found. The roles of the Pharmacy and the Partner must be defined in writing and included in the SOPs.
- 3.11 A method of recording which pharmacist was responsible for final check is required for every dispensed medication. The suggested methods include:
- a) Initialing and dating each hard copy of the prescription checked.
 - b) If checking in a computer system, a list of all prescriptions checked with prescription or order number, patient name, medication, strength and amount dispensed is printed at the end of the day, and the pharmacist signs each page, indicating he or she has done the final verification check for all prescriptions.
- If a different method is used, it should be clearly detailed in the SOPs.

3.12 A hardcopy record of all prescriptions dispensed must be signed by the pharmacist if using 3.11.a above, or the daily reports per 3.11.b. The record must be safely stored on the premises of the dispensing pharmacy for a period of two years from the date of dispensing.

If using methods other than 3.11.a or 3.11.b, appropriate documentation shall be maintained and readily retrievable for a period of two years from the date of dispensing.

Dispensing Area

The pharmacy must have sufficient facilities to carry out dispensing activities in a responsible and safe manner.

3.13 The layout of the dispensing area must promote safe and efficient flow of work and allow for effective communication and supervision.

3.14 Where medications are dispensed there must be adequate:

- Heating/Air Conditioning
- Lighting
- Ventilation

3.15 The dispensing area may not involve any non-dispensing activities.

3.16 Waste must be dealt with in a manner that ensures confidentiality of patient information.

3.17 Dispensing incidents are to be recorded and regularly reviewed with all staff members so that strategies to prevent future incidents are implemented.

IV. Drug Safety

The pharmacy must comply with the pharmacy laws of the country in which it operates. All medications dispensed by the pharmacy must be considered safe and effective, manufactured under Good Manufacturing Practices (GMP) and approved for retail sale in at least one of the following countries: Australia, Canada, European Union members, India (subject to the restrictions of 4.9), Israel, New Zealand, Singapore, South Africa, Switzerland, Turkey, United Kingdom, or the United States. Other countries may be added at the discretion of PharmacyChecker.

Definitions

“Ethically promoted pharmaceutical products” – pharmaceutical products approved for sale that are marketed by a company under a brand name, directly promoted to prescribers by the company, and through the company’s branded division.

“First-tier manufacturer” – a multi-national pharmaceutical company is one that sells products for multiple markets including Australia, Canada, New Zealand, United States, or countries of the European Union who acceded to EU membership before 2002. For example, Cipla and Sun Pharmaceuticals are examples of first-tier manufacturers.

“Global pharmaceutical company” – a pharmaceutical company that is based in Australia, Canada, New Zealand, United States, or countries of the European Union who acceded to EU membership before 2002, that sells pharmaceutical products to the aforementioned countries.

“U.S. FDA/cGMP” – standards for manufacturing pharmaceutical products found in the United States Code of Federal Regulations, 21 CFR 211, subparts A to K, as interpreted by a qualified inspector.

Requirements:

- 4.1 There must be a procedure for ordering and checking incoming medications for safety and authenticity. The roles of the pharmacist and staff members must be defined in writing and included in the SOPs.
- 4.2 There must be a medication recall procedure in place that is clearly communicated in writing. The wholesalers supplying medications to the dispensing pharmacy must agree to forward any recall notifications to the pharmacy.
- 4.3 The pharmacy must ensure quality of supply to guarantee authenticity of medications.
- 4.4 The pharmacy must meet regulations in the country in which it operates.
- 4.5 The pharmacy must have a license to operate in the country in which it resides.

- 4.6 Where dispensing medications to customers based in the United States, no medications may be dispensed that are controlled or considered to be habit-forming substances (as per definition of the U.S. Drug Enforcement Agency).
- 4.7 Where dispensing generic medications, patients expecting a brand name drug cannot receive a generic substitute.
- 4.8 Where the pharmacy offers a refund policy in which medications are returned, there must be a separate area provided for the storage and disposal of such medications. Returned medications may not be re-dispensed; they must be disposed in an environmentally responsible manner.
- 4.9 If dispensing pharmaceuticals approved for sale in India, only the following categories of products may be dispensed:
 - 4.9.1 *Ethically promoted* pharmaceutical products manufactured by *first-tier Indian manufacturers* and *global pharmaceutical companies*, and/or
 - 4.9.2 Products manufactured in plants with approval by the U.S. Food and Drug Administration, Canadian Therapeutic Products Directorate, UK Medicines and Healthcare Products Regulatory Agency, Australian Therapeutics Goods Agency, European Medicines Agency, and/or equivalent agencies, and/or
 - 4.9.3 Products manufactured in plants inspected for cGMP by PharmacyChecker or a third party inspector acceptable to PharmacyChecker.

V. Sanitary Condition of Pharmacy

The pharmacy must be kept in a sanitary manner.

Requirements:

- 5.1 The dispensary must be kept clean, tidy and in hygienic condition.
- 5.2 Staff must have a high standard of hygiene.
- 5.3 There must be separate hand-washing facilities available for staff that are located in or adjacent to the dispensary area.
- 5.4 There must be a suitable method of hand drying available wherever hand washing takes place in the dispensary. Suitable methods include hot air drier or disposable towels.
- 5.5 Toilets must be located in such a manner that they do not open directly into the dispensary area.
- 5.6 All other parts of the premises must be maintained in a clean, tidy and hygienic condition including but not limited to:
 - Rubbish containers
 - Staff rooms
 - Storage areas
- 5.7 There must be an Infectious Disease Policy in place that prohibits staff members with active communicable diseases (such as flu) to work in the dispensing area.
- 5.8 There must be a Wound Management policy in place not allowing staff members with open wounds to work.
- 5.9 Standard Operating Procedures must require hand washing at the beginning of the day, after using bathrooms, breaks, and lunch times. In between, hands may be sanitized using alcohol-based hand sanitizers.

If dispensing loose tablets into bottles:

- 5.10 Dispensary surfaces must be covered in smooth, impervious and washable surfaces and maintained in a good state of repair including:
 - Working surfaces
 - Shelves, cupboards and drawers (internal and external)
 - Ceiling
 - Walls

- 5.11 Flooring in the dispensing area must be in a good state of repair and maintained in a clean manner.
- 5.12 Dispensing equipment must be clean and dry.
- 5.13 There must be a record of cleaning of the dispensary area. For example: cleaning schedules and/or logs.
- 5.14 Dispensary waste (pharmaceuticals) must be disposed in a responsible manner that prevents contamination of environment.

VI. Storage

Medications must be stored in a manner that ensures they remain pharmaceutically stable and free from contamination.

Requirements:

- 6.1 Procedures must be in place to ensure medications are dispensed before their expiry date and patients receive medications with the necessary lead time before expiry.
- 6.2 Medications should be stored in their original containers and if not, should be stored correctly (as per manufacturer's instructions) and be sufficiently labeled so that they are still traceable.
- 6.3 All medications must be protected from:
 - Temperature extremes
 - Direct sunlight/light where applicable
 - Moisture
 - Insects, animals, vermin
- 6.4 The ambient room temperature in the dispensing and storage area must be monitored with procedures in place if the temperature exceeds 25°C.
- 6.5 A refrigerator must be provided for storing medications requiring refrigeration. The temperature within the refrigerator must be recorded. Records must indicate that the refrigerator temperature is maintained between 2° and 8°C. The refrigerator must be clean and frost free. It must not contain any non-medication products, or if so must be separated from these in such a fashion to avoid contamination.

VII. Mailing Prescriptions

Dispensed medications must be mailed in accordance with safe practice to ensure they arrive safely to the correct patient.

Requirements:

- 7.1.1 Dispensed medications must be suitably packaged for mailing to prevent deterioration or crushing. Bubble wrap or filler must be used to prevent movement inside cardboard cartons.
- 7.2 Mail dispatches should be timed so that there is minimum delay at airports, to the extent possible. This is particularly important in countries where the climate may lead to deterioration of medications.
- 7.3 If medications requiring refrigeration are dispensed, a written policy on packing temperature sensitive drugs must be in place (Refer to PharmacyChecker policy on this issue). Medications requiring refrigeration must be suitably packaged to ensure correct temperature is maintained until delivery.
- 7.4 Packaging must ensure confidentiality.
- 7.5 Return address labels should be used.

PharmacyChecker.com Verification Program

Guide and Standards 1.3

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